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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,444	05/18/2005	Samuel J. Shuster	14848-004US1	2312

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EXAMINER	
MCGARRY, SEAN	
ART UNIT	PAPER NUMBER
1635	
MAIL DATE	DELIVERY MODE
05/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,444	SHUSTER ET AL.	
	Examiner	Art Unit	
	Sean R. McGarry	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *1-3 and 15-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/11/05;4/9/07;7/10/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I and the region defined by nucleotides 101-156 in the reply filed on 2/19/08 is acknowledged. The traversal is on the ground(s) that all of the claimed antisense compounds share a common structure since they all bind to an mRNA defined by SEQ ID NO: 2 and that all of the claimed compounds belong to the same art recognized class. While this argument is not agreed with for the reasons set forth in the restriction requirement of 9/17/07 it is submitted that applicant has not addressed the cited prior art that destroys any special technical feature which indeed renders applicant argument moot even if they were persuasive. It is noted that the restriction requirement of 9/17/07 inadvertently did not address claim 14. Claim 14 is included in the instantly elected group and will be examined herein.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1, 2, 3, and 15-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 2/19/08.

Claim 4 is objected to because of the following informalities: Claim 4 recites nonelected subject matter. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 4-7, 10, 11 and 14 are rejected under 35 U.S.C. 102(a) as being anticipated by Hartness et al [Cited by applicant on IDS filed 7/10/07].

Hartness discloses a phosphorothioate antisense oligonucleotide that corresponds to nucleotides 88-106 of the instant SEQ ID NO: 2. It is disclosed that this oligonucleotide targets TASK-3 and is comprised in a lipofectamine carrier composition. It is disclosed that this antisense oligonucleotide also targets the start codon region of TASK-1 mRNA indicating that each antisense in the composition does indeed target different accessible region. The antisense of Hartness et al meets all of the structural requirements of the instant claims.

> **"[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency' under 35 U.S.C. 102, on prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. *In re Fitzgerald,* 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting *In re Best,* 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).**
>
> **MPEP 2112.01:**
>
> **PRODUCT AND APPARATUS CLAIMS X WHEN THE STRUCTURE RECITED IN THE REFERENCE IS SUBSTANTIALLY IDENTICAL TO THAT OF THE CLAIMS, CLAIMED PROPERTIES OR FUNCTIONS AREPRESUMED TO BE INHERENT**

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4-11 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hartness et al [Cited by applicant on IDS filed 7/10/07] in view of Bennett et al.

The invention is as clearly set forth in the claims above.

Hartness discloses a phosphorothioate antisense oligonucleotide that corresponds to nucleotides 88-106 of the instant SEQ ID NO: 2. It is disclosed that this oligonucleotide targets TASK-3 and is comprised in a lipofectamine carrier composition. It is disclosed that this antisense oligonucleotide also targets the start codon region of TASK-1 mRNA indicating that each antisense in the composition does indeed target different accessible region. The antisense of Hartness et al meets all of the structural requirements of the instant claims except for the sugar modifications and base modifications. Bennett , below provides for general antisense teaching including the modifications above.

Bennett et al have taught general targeting guidelines at columns 3-4, for example. It has been taught to target 5'untranslated regions, start codons, coding regions, and 3'untranslated regions of a desired target, for example. It has been taught in column 5, for example, that antisense compounds are commonly used as research reagents and diagnostics, for example. At column 5 it has been taught that antisense oligonucleotides 8-30 nucleotides in length are particularly preferred. At columns 6-7 it has been taught preferred antisense oligonucleotides contain modified internucleoside linkages including phosphorothioate linkages, for example. At columns 7-8 it has been taught that preferred antisense oligonucleotides comprise modified sugar moieties including2'-O-methoxyethyl. It has also been taught to modify nucleobases in antisense oligonucleotides at column 8-9 which includes the teaching of 5-methyl cytosine and at column 10 it has been taught chimeric antisense oligonucleotides. All of the above referred to modification are known in the art to provide beneficial attributes to antisense

oligonucleotides such as increased hybridization and nuclease protection, for example. At columns 10-24, for example it has been taught numerous “carriers” for antisense oligonucleotides.

The prior art therefore teaches an antisense oligonucleotide that hybridizes within the recited region of the invention and further teaches all of the modifications recited in the claims.

The invention as a whole would therefore have been *prima facie* obvious to one in the art at the time was made.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hartness et al [Cited by applicant on IDS filed 7/10/07] in view of Bennett et al as applied above, and further in view of Branch et al.

Claim 11 includes that limitation that embraces a composition that comprises more than one distinct antisense compound targeted to TSK-3 mRNA.

Branch et al disclose that it was known to use “molecular triangulation” in antisense techniques where multiple antisense are deployed against different sites of the same target gene(see page 48, third column).

The prior art has taught antisense targeted to the required target region of the instant invention and furthermore the art teaches to use multiple antisense targeted to different sites on a known target mRNA.

The invention as a whole would therefore have been *prima facie* obvious to one in the art at the time the invention was made.

Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hartness et al [Cited by applicant on IDS filed 7/10/07] and Noonberg et al [US 5,624,803].

The invention is as clearly set forth in the claims above.

Hartness discloses a phosphorothioate antisense oligonucleotide that corresponds to nucleotides 88-106 of the instant SEQ ID NO: 2. It is disclosed that this oligonucleotide targets TASK-3 and is comprised in a lipofectamine carrier composition. It is disclosed that this antisense oligonucleotide also targets the start codon region of TASK-1 mRNA indicating that each antisense in the composition does indeed target different accessible region. Hartness et al do not teach a nucleic acid construct for expressing the antisense targeted to TASK-3.

Noonberg et al have taught in vivo nucleotide generators. It is disclosed that the oligonucleotide generators are nucleic acid constructs that contain regulatory elements such as pol III promoters for the efficient expression of oligonucleotides such and antisense oligonucleotides. It has been taught that the oligonucleotide generators provide for effective delivery of antisense oligonucleotides in cell.

One in the art would be motivated to modify the antisense of Harness to be provided by an oligonucleotide generator to provide for efficient cellular delivery of antisense.

The invention as a whole would therefore have been prima facie obvious to one in the art at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R. McGarry whose telephone number is (571) 272-0761. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Douglas Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sean R McGarry
Primary Examiner
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